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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/030,944

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Alfred Jonczyk

MERCK 2360

6331

23599

7590

01/10/2006

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EXAMINER

GUDIBANDE, SATYANARAYAN R

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/030,944

Applicant(s)

JONCZYK ET AL.

Examiner

Satyanarayana R. Gudibande

Art Unit

1654

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/19/2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of group I invention (claims 1-7) and election of species compound 271593 listed in Table 1 in the reply filed on November 18, 2005 is acknowledged. The traversal is on the ground(s) that all claims in the application involve related subject matter, e.g., cyclopeptides as recited in claim 1. This is not found persuasive because the compounds are distinct because they have different chemical structures and properties, and none would render any of the other obvious. Search for distinct compounds are conducted based on their structure-function relationship with regard to non-patented literature. Therefore, search for one compound would not lead to the discovery of another.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's elected species is free of prior art. Examiner has searched the species recited in claim 3 and have been found to be free of art.

Claims 8 and 9 are withdrawn from consideration as being drawn to non-elected invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Pierschbacher, et al., Proc. Natl. Acad. Sci., 1984, 81, 5985-5988.

In the instant application, applicants claim peptide derivatives of formula I.

Pierschbacher, et al., teaches a tetra-peptide sequence that is the minimal structure recognized by cells in the large glycoprotein fibronectin. The tetra-peptide represents one of the derivatives of formula-I of the instant application. Examiner has broadly interpreted the term 'derivatives' as recited in the claims 1 and 2. The dictionary definition of 'derivative' is 'something obtained or produced by modification of something else'. Therefore, the tetra-peptide of Pierschbacher, et al., reference meets the limitations of the claims.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for six residues of  $\alpha$ -amino carboxylic acid (Gly) residues or one or two residues of Aee or Aha, does not reasonably provide enablement for 7-12 residues of these amino acids (from table on page 5 of specification). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

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or use the invention commensurate in scope with these claims. Because, 12 Gly residues will be ~ 4440 pm in length and 12 Aha residues will be ~10,000 pm in length.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically:

In claims 1-7, applicants claim derivatives of formula-I and their physiologically acceptable salts and their solvates as medicaments. Vippagunta, et al., (Advanced Drug Delivery Review, 2001, 48, 3-26) have studied the formation of hydrates and solvates of pharmaceutically active substances. Solvates are formed when a pure organic solvent or a mixture of organic solvents is used for crystallizing the compound (Section 3.1, page 15). The reference teaches that predicting the formation of solvates or hydrates of a compound and the number of water or solvent molecules associated or incorporated into the crystal lattice of a molecule is complex and difficult (section 3.4, page 18). Since each solid compound responds uniquely to the possible formation of solvates and hence generalizations cannot be made for a series of related compounds. In the instant case, applicants claim solvates of myriads structurally distinct compounds represented by formula-I. The specification has not provided working examples of how these solvates are made for any of the innumerable compounds represented by formula-I nor described the physical structure of any solvate. Therefore, the foregoing arguments are indicative

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of the fact that applicants have not provided adequate written description to show possession of the solvates.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 -7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claims 1-4 recite derivatives of formula-I, 'and' their physiologically acceptable salts 'and' their solvates. It is unclear from the recited claim whether the applicants are claiming 'a derivative' of formula-I and it's physiologically acceptable salt or solvate; or the applicants are claiming any and all possible derivatives of formula-I, their physiologically acceptable salts and their solvates.

Claim 2 recites the limitation " $\text{H}_2\text{N}-(\text{CH}_2\text{CH}_2\text{O})_m\text{-COOH}$ , m, n in each case independently of one another are 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 or 12 with the proviso that  $m+n$  is  $> 0$ " in claim 2. There is insufficient antecedent basis for this limitation in the claim. To begin with,  $\text{H}_2\text{N}-(\text{CH}_2\text{CH}_2\text{O})_m\text{-COOH}$  does not have 'n' in the formula. The proviso that  $m+n > 0$  lends the claim indefinite.  $\text{H}_2\text{N}-(\text{CH}_2\text{CH}_2\text{O})_m\text{-COOH}$  formula does not represent ' $\omega$ -amino carboxylic acid', but it is a modified polyethylene glycol.

Claims 5-7, recites the limitation "medicament" in claims 5 and 6. There is insufficient antecedent basis for this limitation in the claim. Because, the term 'medicament' is confusing and lacks antecedent basis for two reasons: 1) the term 'medicament' is singular, while

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the claim 4 has been drawn to 'compounds of formula-I' which is plural, and 2) it depends on claim 4 which is drawn to peptides and not medicaments.

***Conclusion***


Claims 1 -7 are rejected and claims 8 and 9 are withdrawn from consideration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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